

**Vermont Department of Health
Medication Assisted Therapy for Opioid Dependence Rules
Revised May 31, 2011**

AUTHORITY, PURPOSE, AND ESSENTIAL REQUIREMENTS

I. Authority

These rules are established under authority of 18 VSA Chapter 92 which authorizes the Department of Health to establish comprehensive guidelines, by rule, for a regional system of opiate addiction treatment.

II. Basic Definitions:

SOTA: State Opioid Treatment Authority, as designated by the Vermont Department of Health, Commissioner.

MAT/OBOT: Inter-changeable terms for office based narcotic replacement treatment, per DATA 2000 regulations

OTP: Opioid Treatment Program as defined by federal statute

III. Purpose

These rules constitute minimum requirements for a regional system of opiate addiction treatment and are based upon the Center for Substance Abuse Treatment (CSAT) Guidelines for the Accreditation of Opiate Treatment Programs, revised in 2007. These rules, in compliance with Vermont Statute, also apply to Buprenorphine programs or prescribers who consistently have greater than 30 patients on narcotic replacement partial agonist treatment.

IV. Requirements

Prior to operating, opiate addiction treatment programs must receive written approval by the Vermont Department of Health. Any program seeking approval to provide opiate addiction treatment must comply with the following essential requirements:

A. Behavioral Therapy

Patients must receive appropriate, comprehensive behavioral therapy from a licensed clinical professional. Examples of these providers include: LADC, LCMHC, LICSW, Licensed Psychologist, and/or Licensed Psychiatrist, who is providing intervention beyond pharmacological management.

B. Continuation and Cessation of Pharmacological Treatment

Programs continue medication-assisted treatment as long as the patient derives benefit from treatment, desires continued treatment and the physician is in agreement to continue the treatment. There should be no fixed length of time in treatment. In

fact, indefinite medication-assisted treatment may be clinically indicated. The physician should also be prudent in considering other medications during the course of treatment, as clinically indicated.

C. Dispensing of Pharmacological Treatments

Federally approved pharmacological treatments for opiate addiction must be dispensed *only* by authorized treatment programs/providers.

D. Education and Training Requirements

Comprehensive education and training requirements must be established, including relevant aspects of behavioral therapy and pharmacological treatment, for physicians, pharmacists, and certified or licensed alcohol and drug abuse/Behavioral Health counselors affiliated with an approved treatment program. For technical assistance identifying specific training options, please contact the Vermont Department of Health, Division of Alcohol and Drug Abuse Programs.

E. Rules of Conduct

Rules of conduct for patients must be established in writing with clear description of violations which may result in discharge from the treatment program. These rules must include participation in required urinalysis at such times as the program may direct. Patients must abide by the restrictions on medication dispensing which are designed to prevent diversion of medications and to diminish the potential for patient relapse.

F. Requirements for Approval

1. The Health Department Commissioner may approve an OTP/OBOT/MAT program which has been accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), CARF - the Rehabilitation Accreditation Commission, or the Commission on Accreditation (COA) for the term of the accreditation if the program also meets any additional standards and criteria established by these rules (Appendix A).
2. The Health Department Commissioner may approve an OTP/OBOT/MAT provider which has been reviewed by ADAP and found to be in compliance with standards and criteria established by these rules (Appendix A). If a program does not fully meet the standards and criteria, the Commissioner may:
 - a. Not award Program Approval until such time as full compliance is met;
 - b. Award Conditional Approval valid for ninety days. If the program demonstrates full compliance with the standards and criteria during that time, Program Approval will be awarded.
 - c. Program Approval will be valid for a period of up to three years.
3. The Commissioner, at his/her discretion, may upon request grant a waiver of approval requirements for individual MAT/OBOT practitioners who meet specified criteria that are consistent with the expectations specified within this document.

G. Appeals

1. If the Commissioner denies program approval, the applicant shall be afforded an opportunity for a hearing with the Commissioner of Health pursuant to the provisions of Chapter 25, Title 3, VSA.
2. An appeal of a decision of the Commissioner of Health may be made to the Secretary of the Agency of Human Services, and an opportunity for a hearing with the Secretary will be given pursuant to the provisions of Chapter 25, Title 3, VSA.

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OPIATE TREATMENT APPROVAL RULES

These rules are based on the Center for Substance Abuse Treatment (CSAT) *Guidelines for the Accreditation of Opiate Treatment Programs*, revised 2007, and have been written to comply with Vermont statute. These rules will also apply to Buprenorphine programs or prescribers who consistently have greater than 30 patients on narcotic replacement partial agonist treatment

I. Introduction

Treatment Considerations Related to the Natural History of the Disease

The clinical assessment of all patients should take into account the natural history of opiate addiction as altered by time and treatment. Patients normally proceed from one stage of treatment to the next, or move back and forth among the naturally occurring stages.

The stages of pharmacological treatment therapy are listed below. It is important at all stages that psychosocial, as well as medical treatment, be of sufficient intensity and duration to be effective.

1. Initial treatment/Induction: consisting of intensive assessment and intervention, from 2 to 7 days in duration.
2. Early stabilization: from the third to seventh day of treatment through 8 weeks
3. Long-term treatment/Maintenance: from the end of early stabilization for an indefinite period of time.
4. Medically supervised withdrawal with continuing care, if and when appropriate.

The patient's response to treatment determines her or his progression through the stages of treatment. Some patients may sometimes remain in one stage for a considerable period of time while, in contrast, others may progress very quickly. It is not uncommon for a patient to relapse.

I. Administrative Organization and Responsibilities

Administrative responsibilities, both for organizations and individual practitioners, are adequate to ensure quality patient care and to meet the requirements of the laws and regulations of the U.S. Department of Health and Human Services, Drug Enforcement Administration, and the State of Vermont.

Physician authority over the medical aspects of treatment is essential. Physicians retain the autonomy to make continuing treatment decisions in accord with clinical course and emergent research findings.

Each provider will develop a referral and consultative relationship with a network of agencies and providers capable of providing primary and specialty services for the range of behavioral difficulties, psychiatric comorbid conditions, medical complications, and communicable

diseases that may be part of a patient's problem list. Information exchange across this network must both facilitate treatment and protect patient privacy.

A. Mission Statement and Goals

Each treatment program shall have a written statement of its mission and/or goals for patient care.

B. Human Resources Management

Programs maintain individualized personnel files as a record of employment. These files contain employment and credentialing data deemed appropriate by the employer. The files also contain employment application data, date of employment, updated licensing and credentialing data, detailed job descriptions, performance evaluations, and appropriate intramural and extramural training records.

B. Management of Facility and Clinical Environment

1. Each treatment facility:

- (a) Has sufficient space and adequate equipment for the provision of all specified services, including diagnosis, evaluation, and treatment of other medical, psychiatric, and behavioral disorders, if they are to be carried out onsite
 - (b) Is clean and well maintained.
 - (c) Maintains documentation that it meets all local and State safety and environmental codes
 - (d) Ensures protection of confidentiality, including the use of locked files and the availability of private, individual offices for counseling
 - (e) Provides services during hours that meet the needs of the overwhelming majority of patients, including hours before and/or after the traditional 8:00 a.m. to 5:00 p.m. working day, when possible
- (2) The program sponsor is the person ultimately responsible for the operation of the program. Importantly, the program sponsor is responsible for assuring that the program complies with all Federal, State, and local laws and regulations. (See 42 CFR § 8.2.) If there is a change of sponsor, The Vermont Department of Health; State Opioid Treatment Authority (SOTA) requires formal notification within 30 days and for OTP programs, SAMHSA requires formal notification within 3 weeks of the change.

- (3) The program director or program manager is the person who manages the program operations from day to day, and whose authority is delegated by the program sponsor (who retains ultimate responsibility for program operations). Program directors have varying levels of program responsibility, frequently including the responsibility to hire and fire employees, and carry out multiple management activities, depending on the duties assigned to them by the sponsor. (Not all OTP or Buprenorphine programs have program directors or program managers, and the regulations do not require them. In some OTPs, the program sponsor also acts as the program director.)
- (4) The medical director, or prescribing physician in case of MAT/OBOT, is responsible for monitoring and supervising all medical services provided by the OTP/MAT/OBOT program. Only a licensed physician may serve as the medical director of an OTP (See 42 CFR § 8.2.) and/or prescribe Office Based Opioid Treatment (OBOT/MAT). If there is a change of medical director, the Vermont Department of Health; SOTA requires formal notification within 30 days and for OTP programs SAMHSA requires formal notification within 3 weeks of the change.

II. Quality Improvement

A. Risk Management and Continuous Quality Improvement

1. Life Safety Issues

(a) Each treatment program:

- (i) Develops procedures to ensure that the correct dose of medication(s) is administered and that appropriate actions are taken if a medication error is made. Procedures should include a mechanism for reporting critical incidents to appropriate program staff and the Vermont Dept of Health, State Opioid Treatment Authority (SOTA). In office based situations, this may be more related to prescription accuracy and/or monitoring self-administration during the induction phase of treatment.
- (ii) Provides a mechanism to address patient emergencies by establishing an emergency contact system to obtain dosage levels and other pertinent patient information on a 24-hour, 7-day-a-week basis, as appropriate under confidentiality regulations. Facility offices and waiting areas should display the names and telephone number of individuals (e.g., physicians, hospitals, emergency medical technicians) who should be contacted in case of emergency, or utilize 9–1–1 or similar local emergency resources.
- (iii) Ensures that there are appropriately trained staff members on duty who are trained and proficient in cardiopulmonary resuscitation (CPR), management of opiate overdose, medical emergencies, and other techniques as appropriate.

- (iv) Establishes policies and procedures that address safety and security issues for patients and staff, including training for staff to handle physical or verbal threats, acts of violence, inappropriate behavior, or other escalating and potentially dangerous situations, with emphasis on situations in which security guards or police need to be summoned.

(b) Program Emergencies

Each treatment program:

- (i) Develops, maintains, and updates regularly a disaster plan that addresses maintenance of fire extinguishers, fire drills, emergency evacuation procedures, and that includes links to community agencies. A copy of this plan should be submitted annually, or when changes occur, to the SOTA thru the Vermont Dept. of Health.
- (ii) Maintains a 24-hour telephone answering capability to respond to facility emergencies. A record of patients and medication dosages is accessible to the staff person on call for verification purposes.
- (iii) Maintains an up-to-date plan for emergency administration of medications in case the program must be closed temporarily. The plan should include a mechanism for informing patients of these emergency arrangements. For office based programs (OBOT/MAT), the plan should identify emergency procedures for obtaining prescriptions/access to medications in case of temporary program/office closure. Such plans may include a cooperative agreement with the local Emergency Department or another physician to at minimum utilize the 72 hour rule in case of brief shut down/lack of availability.
- (iv) Ensures that needed supplies are available in the event of an emergency.

(2). Continuous Quality Improvement Policies

Each treatment program

- (a) Provides regular and continuous staff education.
- (b) Maintains staff development plans.
- (c) Reviews and recertifies program policies and procedures at least annually.
- (d) Elicits ongoing input into program policies and procedures by patients in consideration of community concerns.
- (e) Develops and implements periodic patient satisfaction surveys.
- (f) Adheres to universal or standard infection control precautions promulgated by the Centers for Disease Control and Prevention (CDC) and the Vermont Occupational Safety and Health Administration (VOSHA) requirements.

(g) Measures and monitors treatment outcomes and processes on a regular basis—for example, quarterly—to provide feedback on measures of performance. Monitors and measures treatment outcomes such as

- (i)** Reducing the illicit use of illicit opioids, illegal drugs, and the problematic use of alcohol and prescription medicines
- (ii)** Reducing associated criminal activities and entry into the criminal justice system
- (iii)** Reducing behaviors contributing to the spread of infectious diseases
- (iv)** Improving quality of life by restoring physical and mental health and functional status
- (v)** Increasing retention in treatment, as appropriate
- (vi)** Increasing numbers of patients who are employed
- (vii)** Increasing abstinence from drugs of abuse

(3) Events That Require Immediate Response and Investigation

Each treatment program

(a) Establishes procedures to guard against critical incidents, which are defined as any events that could have a negative impact on patients and their family members and the program or staff. This includes events that involve the loss of life or function, any serious physical or psychological injury, and medication errors. Critical events are also known as sentinel events, significant adverse events, and untoward events.

(b) Establishes procedures, in case a critical incident occurs, to ensure

- (i)** Full documentation of the incident
- (ii)** Prompt investigation and review of the situation surrounding the incident
- (iii)** Implementation of timely and appropriate corrective action(s)
- (iv)** Ongoing monitoring of any corrective actions until their effectiveness is established

(c) Reports each critical incident to the appropriate accrediting organization, and the Vermont Department of Health, State Opioid Treatment Authority (SOTA), consistent with procedures established by these organizations. Examples of reportable critical incidents involving patient deaths include:

(i) Drug-related deaths

(ii) Methadone or buprenorphine deaths

(iii) Unexpected or suspicious deaths

(iv) Treatment-context deaths that raise individual, family, community, or public concern

(d) As appropriate, report critical incidents to the Food and Drug Administration (FDA) Adverse Event Reporting Program regarding (MedWatch, <http://www.fda.gov/medwatch/>; at 1-800-332-1088). Examples of reportable critical incidents include

(i) Serious adverse events and medications errors

(ii) All types of deaths related to any drug

(4) Voluntary and Involuntary Program Closure

(a) Programs develop a plan to establish, through State authority, procedures to ensure continuity of care for patients in the event of voluntary or involuntary closure of programs or individual medical practices. The plan includes steps for the orderly transfer of patients, records, and assets to other programs or practitioners.

(1). With as much advanced notice as is reasonable, to the situation, (30 days minimum) the program/provider will contact the Vermont Department of Health; SOTA to discuss the rationale for the closure, contacts made and efforts to date to establish continuity of care for patients. It is anticipated that providers/programs experiencing difficulties will demonstrate all due diligence to ensure patients have access to reasonable care and to access available state and community resources to ensure successful outcomes for the situation.

(b) Programs develop a plan to ensure that patient records from programs that are closing are secured and maintained for a specified period of time in accordance with State and Federal regulations.

(5) Diversion Control

Each program has a diversion control plan (DCP) that demonstrates accountability to its patients and to the community. The DCP also should demonstrate the efficient use of personnel and other resources to achieve the highest quality of patient care, while reducing possibilities for diversion of controlled substances from legitimate treatment to illicit use.

Diversion of both the mono and combination buprenorphine preparations present additional challenges, due to the office based nature of OBOT/MAT. Physicians must inform patients that diversion is a reportable criminal offense, and indicate how suspicions or evidence of diversion will be handled clinically by the practice. Practices should have clinical procedures in place for minimizing diversion risk to ensure appropriate addiction treatment, such as the following:

- Routine toxicology screens
- Pill call backs (for counting)
- Bubble packing of prescriptions

MAT/OBOT Prescribers shall register with the *Vermont Prescription Drug Monitoring System (VPMS)*, established by the Vermont Department of Health to provide health care professionals to provide an electronic database and reporting system for electronic monitoring of prescriptions for controlled substances. The VPMS may be accessed online by registered prescribers and pharmacists at <http://healthvermont.gov/adap/VPMS.aspx>. Additional information is available through the Alcohol and Drug Abuse Programs (ADAP) office at 802-652-4147.

(6) Community Relations and Education

For existing and/or new programs, to help minimize negative impact on the community, promote peaceful coexistence, and plan for change and program growth, programs develop and implement a general set of practices, policies, and/or procedures that

- (a) Consider community need and impact in selecting sites for programs
- (b) Elicit input from the community on the program's impact in the neighborhood
- (c) Ensure that the facility's physical appearance is clean and orderly and that the physical setting does not impede pedestrian or traffic flow
- (d) Identify community leaders for the purpose of fostering good community relations, and establish interpersonal contact and proactive associations with identified leaders (e.g., publicly elected representatives; local health, substance abuse, social, and/or human service agency directors; business organization leaders; community and health planning agency directors; grassroots community organization leaders; local police and law enforcement officials; and religious and spiritual leaders)
- (e) Develop and support a community relations plan, specific to the configuration and needs of the program within its community that includes the following steps:
 - (i) Establishing a liaison with community representatives to share information about the program, the community and mutual concerns and issues

- (ii) Identifying program personnel who will function as community relations coordinators and define the goals and procedures of the community relations plan
- (iii) Serving as a community resource on substance abuse and related health and social issues, as well as promoting the benefit of medication-assisted treatment in preserving the public health
- (iv) Soliciting community input about medication-assisted treatment and the program's presence in the community
- (v) Developing program policies and procedures to effectively address or resolve community problems (including patient loitering and medication diversion), and ensuring that program operations do not affect community life adversely
- (f) Document community relations efforts and community contacts, evaluate these efforts and contacts over time, and address outstanding problems or deficiencies
- (g) Devise communication mechanisms so that interested parties and potential patients may obtain general information about the program outside regular operating hours

(7). Professional Staff Credentials and Development

Each treatment program ensures the following:

- (1) Doctors, nurses, and other licensed professional care providers maintain current licenses and comply with the credentialing requirements of their own professions. Specific credentialing for work in addictions, by any formal body, is desirable, but not required.
- (2) Before staff members provide care to patients, they receive initial education specific to the medication-assisted treatment(s) used in the OTP/OBOT/MAT program and tailored to the patient populations served.
- (3) Staff members receive continuing education on opioid addiction treatment and related subjects.
- (4) The OTP/OBOT/MAT program implements an individual annual training plan for each staff member.
- (5) The OTP/OBOT/MAT programs develop job descriptions for credentialed and non-credentialed staff. Job descriptions clearly define the qualifications and competencies needed to provide specific services.
- (6) Records of staff training events are kept and include the qualifications of educators, outlines of content, descriptions of methods, and rosters of attendees. OTPs /OBOT/MAT programs maintain records of staff training events in personnel files.
- (7) Resources for problem solving and troubleshooting are accessible.

- (8) There are an adequate number of physicians, nurses, counselors, and other staff for the level of care provided, related to the number of patients enrolled in the program.

III. General Program Standards

(A) Patient Admission Criteria

(1) Evidence of Current Physiological Dependence and Opioid Addiction

- (a) The program physician must diagnose opioid addiction or dependence, as defined in either the current edition of the Diagnostic and Statistical Manual of Mental Disorders, or the current edition of the International Classification of Diseases, document that diagnosis, and admit each patient to maintenance or detoxification treatment as medically necessary. If pharmacological treatment is medically appropriate, a medical assessment conducted for the appropriateness of treatment with buprenorphine, prior to prescribing methadone.
- (2) Patients often exhibit the physical signs and symptoms of opioid dependence. Onsite (“point of collection”) test devices may be useful in screening a patient’s current physiological dependence.
- (3) A 1-year history of addiction is necessary for admission to an OTP/OBOT/MAT **maintenance** treatment program. Individuals with less than a 1 year history of dependence may require pharmacological intervention, however **medically supervised withdrawal** would be the rationale for admission rather than the expectation of long-term maintenance. The absence of current physiological dependence should not be an exclusion criterion, and admission is clinically justified. OTP/OBOT/MAT providers can accept arrest and medical records, information from significant others and relatives, and other information to document the 1-year history of addiction.
- (4) For populations of individuals who have a history of narcotic dependence however who may not have any current or active use, such as those being released from penal institutions or previously treated patients, Federal OTP regulations waive the 1-year history of active addiction for these special populations. However in MAT/OBOT situations it is **strongly** recommended that consultation with a substance abuse clinician knowledgeable in opioid replacement therapy, an addiction specialist, or a treatment team member from the Vermont Department of Health; Division of Alcohol and Drug Abuse Programs be consulted to discuss the situation including alternative treatment and/or pharmacological strategies.
- (5) A physician assesses each patient before admission to medication-assisted treatment. The exceptional circumstance is that the physician may review the medical examination performed by another qualified health professional by phone or fax, make the required diagnosis, and admit the patient. The physician would then review and countersign the patient record within 72 hours. Standing orders for admitting patients are not acceptable. It is fully expected that unless an exceptional circumstance exists, the medical director and/or prescribing physician will have done a face-to-face assessment of the patient prior to commencing dosing. In cases of exceptional circumstances, it is still expected for this face-to-face assessment to occur within the 72 hours following commencement of dosing.

B. Informed Consent

Each treatment program

- (1) Obtains voluntary, written, program-specific informed consent to treatment from each patient at admission. Releases of information for all ancillary individuals/providers should also be obtained with each patient receiving a copy and 1 copy of each form for the record
- (2) Informs each patient about all treatment procedures, services, and other policies and regulations throughout the course of treatment.
- (3) Before medicating the patient, obtains voluntary, written, informed consent from each patient to the specific pharmacotherapy ordered by the physician. In cases of OBOT/MAT a copy of the Buprenorphine Treatment Agreement should also be forwarded to the identified pharmacy
- (4) Informs each patient of the following:
 - (a) That the goal of medication-assisted treatment is stabilization of functioning.
 - (b) That, at periodic intervals, in full consultation with the patient, the provider discusses present level of functioning, course of treatment, and future goals. These discussions should not place an unfair burden or pressure on the patient to withdraw from medication or to remain on medication maintenance unless medically indicated.
- (5) Informs each patient, at admission, about State-specific requirements and program policies regarding the report of suspected child abuse and neglect, as well as other forms of abuse (e.g., violence against women).
- (6) Adheres to all requirements of the Federal confidentiality regulations (42 CFR Part 2) and HIPAA (45 CFR Part 160 and Subparts A and E of Part 164).
- (7) Promulgates and makes available a written description of patients' rights and responsibilities.

C. Patient Medical and Psychosocial Assessment

The purpose of an assessment is to determine treatment eligibility, obtain sufficient information to develop a treatment plan, and establish a measure for the response to treatment. For all applicants initially deemed eligible for medication-assisted treatment, program staff members complete a comprehensive physical examination, laboratory workup as indicated, psychosocial assessment, preliminary treatment plan, and patient orientation during the initial treatment stage.

(1) Assessment and Medical Evaluation

At a minimum it is expected that patients receive:

(A) Comprehensive Psychosocial Assessment:

It is expected that a comprehensive psychosocial evaluation be completed on all patients receiving medication assisted treatment. IN OTP/OBOT/MAT programs with on-site licensed, Behavioral Health clinicians, it is expected that this assessment be completed by the 3rd visit. For those OBOT/MAT providers without co-located Behavioral Health Clinicians, it is anticipated that these individuals are referred for behavioral therapy supports and that releases are signed such that the prescriber obtains a copy of this assessment from the referred clinician.

(B) A comprehensive physical examination inclusive of the patient: health history, identification of other chronic or acute health conditions, current objective measures of health, pregnancy status of female patients, and selected labs/medical evaluations as further defined and matched with patient identified needs.

(C) Completes a psychiatric history and mental status examination with DSM-IV-TR (APA 2000) categorization.

(D) The program completes assessment updates and treatment plan updates **quarterly for the first year** of continuous treatment. In subsequent years, the **OTP updates** assessments and treatment plans **semiannually** while the **OBOT/MAT** providers should **continue quarterly**. If the OBOT/MAT program does not have on-site behavioral and/or substance abuse counseling, it is expected that the medical provider obtain a copy of the completed evaluation from the clinician to whom the patient was referred for therapies.

(vii) Triage and refers patients who have the need for services not provided by the OTP/MAT/OBOT to other care providers, as appropriate.

(viii) For patients referred elsewhere, ensures that the exchange of information conforms to confidentiality regulations for patients in drug or alcohol treatment (42 CFR Part 2) and HIPAA regulations (45 CFR Part 160 and Subparts A and E of Part 164).

(2) Medical Laboratory Evaluation/Diagnostic Criteria

Based on an individual's history and physical examination, programs evaluate the possibility of infectious disease, liver or pulmonary conditions, cardiac abnormalities, psychiatric problems, dermatologic sequelae of addiction, and possible concurrent surgical and other problems by conducting testing or referring patients for consultation and testing.

(a) Recommended tests and assessments, as medically appropriate, include the following:

(i) Vital signs, including blood pressure, pulse, respirations, and temperature

(ii) TB skin test and chest x ray, if skin test is positive (including consideration for anergy)

(iii) Screening test for syphilis

- (iv) Complete blood count (CBC) and lipid panel
 - (v) Electrocardiogram (EKG), chest x ray, Pap smear, and screening for sickle cell disease
 - (vi) Liver function tests and viral hepatitis marker tests
 - (vii) HIV testing and counseling
 - (viii) Tests appropriate for the screening or confirmation of illnesses or conditions, as recommended by U.S. Preventive Services Task Force or based on concerns specific to the patient regarding renal function, electrolyte imbalance, metabolic syndromes, pain, and so forth
 - (ix) Pregnancy test for any woman of child bearing age within 14 days prior to induction of pharmacotherapy
 - (x) Appropriate neurological or psychological testing and assessment, as indicated
 - (xi) Based on baseline screening tests, appropriate referral for more diagnostic testing, especially when those results have potential to significantly change treatment decisions (such as when a screening EKG suggests a prolonged QT interval in a symptomatic patient)
- (b) Programs conduct an initial toxicology test as part of the admission process. Programs test admission samples for opiates, methadone, amphetamines, cocaine, marijuana, benzodiazepines, and alcohol at the minimum. Future toxicology panels should be at the discretion of the physician, based upon clinical judgment and trends within local drug use
- (c) Other considerations include the following:
- (i) Financial problems, transportation to referral sites, stress, and poor mental and physical well-being may be barriers to comprehensive laboratory testing on admission. Other tests may be deferred until the patient has stabilized.
 - (ii) Patients may also require other health care. Programs without primary care onsite should refer patients for laboratory tests and follow up on results. The optimal deadline for completing needed health-related procedures is 3 months after admission, per OTP guidelines though contraindications to potential pharmacological agents should be identified prior to induction.

(3) Treatment Planning, Evaluation of Patient Progress in Treatment, and Continuous Clinical Assessment

(A) Treatment Considerations Related to the Natural History of the Disease

The clinical assessment of all patients should take into account the natural history of opioid addiction as altered by time and treatment. Patients normally proceed from one stage of treatment to the next or move back and forth among the naturally occurring stages. Treatment tasks are determined in relation to the patient's stage in recovery.

As mentioned prior, the stages of medication-assisted treatment are listed below. It is important at all stages that psychosocial treatment, as well as medical treatment, be of sufficient intensity and duration to be effective.

- (a) Initial treatment/Induction: consisting of intensive assessment and intervention, from 3 to 7 days in duration.
- (b) Early stabilization: from the 3rd to 7th day of treatment through 8 weeks.
- (c) Long-term treatment/Maintenance: from the end of early stabilization for an indefinite period, either in a program setting or in an office-based setting.
- (d) Medically supervised withdrawal with continuing care, if and when appropriate.
- (e) Immediate emergency treatment: provision of medication-assisted treatment in situations in which access to a comprehensive treatment program is not feasible for conditions such as pregnancy, HIV-spectrum disease, or other illnesses and psychiatric problems.
- (f) Findings from the initial medical assessment should be reassessed should there be any noted changes in the patient's physical condition or should the patient develop symptoms consistent with adverse events related to specific opioid medication treatment (e.g., developing symptoms consistent with torsades de pointes). Additionally, if there is any change in medication or other drug use documented in the initial and subsequent medical exams, then the clinical staff should pay specific attention to potential medication interactions.

The patient's response to treatment determines her or his progression through the stages of treatment. Some patients may remain in one stage for a considerable period, while, in contrast, others may progress very quickly.

Pharmacotherapy may benefit the individual patient even when he or she does not appear to be benefiting from other clinical services. Additionally, pharmacotherapy may benefit the patient who no longer needs ancillary services. However therapy services are recommended for all individuals during the early stages of OTP/OBOT/MAT and any decisions to discontinue therapy should be addressed by the physician, in conjunction with the counselor and patient.

(B) Intensity and Duration of Treatment

- (a) In general a greater intensity of services is desirable at the beginning of treatment, when staff members identify a patient's relapse or when relapse "trigger" conditions exist. However prevention of relapse use can be accomplished through relapse prevention planning.
- (b) Many patients often need psychosocial services for an extended period because of the multiplicity of their problems.

- (c) For long-term opiate addiction treatment, many patients need continuing medication, with or without psychosocial services, as outlined in TIP 43, “Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs” (CSAT 2005). In MAT/OBOT programs, again communication between the physician, counselor, and patient should be on-going throughout treatment.
- (d) There are no limits on the duration or the dosage level of medication, unless clinically indicated. Likewise, there are no limitations on psychosocial services offered even when patients are receiving “0” dose levels in OTPs.

(3) Retention in Treatment

- (a) Programs and individual practitioners make every effort to retain patients in treatment as long as clinically appropriate, medically necessary, and acceptable to the patient.
- (b) The treatment program takes appropriate therapeutic measures to address the other problems identified in the treatment plan.
 - (C) In OBOT/MAT programs informed consent should consist of discussion of treatment expectations, “clinical appropriateness”, anticipated responses to use of licit/illicit substance, physician tolerance for behavior, and potential alternatives to OBOT/MAT

(a) Voluntary Patient Relocations, Program Transfers, and “Guest Dosing”

When a patient relocates, transfers to another treatment program, or needs temporary care at another program (“guest dosing”), the original OTP/OBOT/MAT program ensures that the patient makes as smooth a transition as is feasible, and the program attempts to avoid breaks in treatment that could lead to relapse.

The original treatment program should forward relevant medical records to the receiving treatment program, with patient consent in accordance with the privacy standards of 42 CFR 2.

(b) Relapse Prevention

- (a) Psychosocial treatment continues for patients electing to discontinue pharmacotherapy in OTP programs while referrals for continued psychosocial supports should be offered to OBOT/MAT patients as needed.
- (b) If possible, clinics and individual practitioners track patients and reinstitute pharmacotherapy at the first sign of relapse or impending relapse. (See N. (3), “Support of Medically Supervised Withdrawal.”)
- (c) Some patients progress into long-term pharmacotherapy and no longer need psychosocial services. If the need for psychosocial services reemerges, however, programs provide the opportunity to return to full services if integrated, otherwise support with referrals is offered.

6. Record Keeping and Documentation

All records required by 42 CFR § 8.12 (g) should be retained for a minimum of 3 years.

(A) Patient Records

Patient records are confidential and updated in a timely manner. They contain legible entries, and are organized in a manner that facilitates access to specific elements of the record, as well as measurement of individual patient treatment outcomes. Programs should have record retention policies and safeguards for the destruction of old containers, labels, printouts, and program records. Program procedures should ensure security of electronic data transfers and protection of confidential data stored in computers. Clear guidelines should exist for access, transfer, and disposal of records, to include procedures under disaster conditions or in the event of program closure, in accordance with 42 CFR 2.

OTP/OBOT/MAT providers are required under 42 CFR §8.11(f) (3) to comply with the Federal confidentiality regulations set forth under 42 CFR Part 2. As such, records of the identity, diagnosis, prognosis, or treatment of any patient that are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the program shall, except as provided in subsection (e) of 42 CFR Part 2, be confidential and be disclosed only for the purposes or circumstances expressly authorized under subsection 42 CFR section 2(b).

Individual records maintained for each patient contain the following:

- (a)** Identification and basic demographic data and results of the screening process. In lieu of patient identification data, each file may bear a unique identifying code that gives reliable access to such required identification information. All information should be accessible and understandable to appropriate authorities.
- (b)** Documentation of compliance with the Vermont Department of Health's central registry system
- (c)** The initial assessment report, with the initial assessment completed by the 3rd visit
- (d)** Medical reports, including results of physical examination; past and family medical history; review of systems; nursing notes; laboratory reports, including results of regular toxicology screens; and progress notes, including documentation of all medications and dosages. Information in the medical record is entered by physicians and/or other licensed health professionals.
- (e)** Dated case entries of all significant contacts with patients, including a record of each counseling session, if applicable, in chronological order.
- (f)** Dates and results of case conferences for patients.

- (g) The treatment plan, and any amendments to it; quarterly reviews and updates of the assessment and treatment plan for the first year of continuous treatment; semiannual assessment/treatment planning for OTP programs or continued quarterly treatment plan updates for OBOT/MAT programs
- (h) Documentation that all services listed in the treatment plan are available, and actually have been provided.
- (i) A written report of the process and factors considered in decisions impacting patient treatment (e.g., take-home medication privileges, changes in counseling sessions, changes in frequency of drug tests, reduced/increased frequency of medical appointments, dosage changes, etc) or any other significant change in treatment, both positive and negative.
- (j) A record of correspondence with patient, family members, and other individuals, and a record of each referral for service and its results.
- (k) Documentation that the patient received a copy of the program's rules and regulations and a statement of patients' rights and responsibilities, and that these items were discussed with her or him.
- (l) Consent forms; release(s) of information; prescription documentation; and travel, employment, "take-home" documentation, and so forth.
- (m) A closing summary, including reasons for discharge and any referral. In the case of death, the cause of death is documented.

(B) Records of Storage, Dispensing, and Administering Opioid Medication

- (a) Each program has policies and procedures consistent with DEA statutes and regulations.
- (b) Each medication order and dosage change is written on an acceptable order sheet signed by the physician.
 - (i) Each dosage dispensed, prepared, or received is recorded and accounted for by signed notation, in a manner that creates a perpetual and accurate inventory of all medications and/or prescriptions, including controlled substances in stock at all times.
 - (ii) Every dose is recorded on an administration sheet, at the time that the dose is administered or dispensed, and recorded on the patient's individual medication dose history.
 - (iii) The qualified person administering or dispensing medications signs his or her name or initials at each notation.
 - (iv) If initials are used, the full signature of the qualified person administering or dispensing appears at the end of each page of the medication sheet.
 - (v) The medication dose is totaled in milligrams daily.

- (c) Programs have a procedure for calibrating medication-dispensing instruments, consistent with manufacturers' recommendations, to ensure accurate patient dosing and substance tracking.

7. Guidelines for Therapeutic Dosage

(A) General Dosage Principles

- (a) The physician employs clinical judgment to determine the individual dose of opioid medication and should have training in medication assisted treatment.
- (b) Maintenance medication doses are sufficient to produce the desired response in the patient for the desired duration of time, with allowance for a margin of effectiveness and safety.
- (c) When necessary to withdraw the patient from opioid treatment, the medically supervised withdrawal protocol will be of sufficient duration for patient safety.
- (d) Effective therapy involving medication-assisted treatment has the following desired outcomes:
 - (i) Preventing the onset of subjective and/or objective signs of opioid abstinence syndrome for at least 24 hours
 - (ii) Reducing or eliminating the drug craving routinely experienced by the patient
 - (iii) Blocking the euphoric effects of any illicitly acquired, self-administered opioids, without inducing undesirable effects experienced by the patient or noticed by other observers.

(B) Maintenance Therapy

- (a) A medical evaluation, including documented history and physical examination, support the judgment by the physician and/or appropriately licensed practitioner that the patient is a suitable candidate for opioid therapy.
- (b) Medication induction should be guided by clinical presentation, patient ability to tolerate the medication and avoidance of negative effects. Federal regulations stipulate that the initial dose of methadone should not exceed 30 mg. with medical discretion to consider a 40 mg total first day administration. Buprenorphine induction guidelines are also prescribed with flexibility to adjust based upon clinical presentation and presenting illness. A copy of the recommended Buprenorphine induction guidelines is located at the back of this document.

C) The total dose of medication and the interval between doses may require adjustments for the patient who has concurrent health conditions or atypical metabolic patterns, or if the patient takes other prescribed medications that alter rates of opioid medication metabolism.

(d) Programs do not adjust medication doses to reinforce positive behavior or to punish negative behavior.

(e) Programs continue medication-assisted treatment as long as the patient derives benefit from treatment, desires treatment, that the treatment is medically necessary and that the patient is considered to be adherent with the established rules of the program.

(f) The program should have the capability to obtain serum methadone levels when clinically indicated and/or urine based buprenorphine/nor-buprenorphine levels

(C) Avoiding Multiple Program Enrollments

(a) Reasonable measures are taken to prevent patients from enrolling in treatment provided by more than one clinic or individual practitioner. These measures are commensurate with the severity of the problem and its documented consequences. In some cases, an OTP may, after obtaining patient consent, contact other OTPs within a reasonable geographic distance (100 miles) to verify that a patient is not enrolled in another OTP. Use of the Vermont Prescription Monitoring System (VPMS) is expected by OBOT/MAT providers.

NOTE: Subutex and Suboxone Treatment for Patients Admitted to OTPs. SAMHSA-certified OTPs are authorized to dispense or administer (but not to prescribe) approved opioid treatment medications to patients admitted for opioid treatment. At this time, methadone and the buprenorphine products, Subutex and Suboxone, are approved for use in OTPs. Such treatment is not subject to the “30-patient limit” placed on physicians certified under the Drug Addiction Treatment Act (DATA) of 2000 or to the 100-patient limit placed on physicians under The Office of National Drug Control Policy Reauthorization Act of 2006. In addition, the special credentialing and 8-hour training requirements under that law do not apply to methadone and buprenorphine treatment for patients admitted to an OTP.

Subutex and Suboxone Treatment for Patients Treated by “Waivered Physicians.” Physicians may seek and obtain a “waiver” under the DATA of 2000. If qualified, the physician is authorized to prescribe or dispense Subutex or Suboxone for up to 100 patients at any given time. The DATA does not limit the treatment settings for physicians with a waiver. Accordingly, the physician may treat patients in an office-based setting, a residential or inpatient facility that is not an OTP, or in an OTP (including as an OTP physician), as long as the total number of patients treated at any one time does not exceed 100.

8. Concurrent Services

(A) Orientation to Treatment

Patients receive orientation to treatment initially and receive ongoing education about

- (a) Signs and symptoms of overdose and when to seek emergency assistance
- (b) The medication they are taking, including side effects and common myths about the medication or modality of treatment
- (c) The nature of addictive disorders
- (d) The benefits of treatment and nature of the recovery process, including phases of treatment
- (e) Clinic guidelines, rules, and regulations, including the requirement to sign a formal agreement of informed consent, and fees and billing procedures
- (f) Noncompliance and discharge procedures, including administrative withdrawal from medication
- (g) Patient's rights
- (h) Confidentiality and how release of information is permitted in accordance with 42 CFR Part 2
- (i) Toxicology testing procedures
- (j) Dispensing medication
- (k) HIV-spectrum and other infectious diseases
- (l) Potential drug interactions
- (m) Agreements required for release of information is permitted in accordance with 42 CFR Part 2

B) Substance Abuse/Behavioral Health Counseling

Appropriately trained, experienced, and qualified counselors provide services of the intensity and duration required to meet the individual needs of the patient population. Programs determine staffing patterns by taking into account the characteristics and needs of particular patient populations. Likewise, patient-to-staff ratios are sufficient to ensure that patients have reasonable and prompt access to counselors, and to provide the required frequency and intensity of counseling services.

In OBOT/MAT programs that do not offer behavioral health counselors within the context of the program, referrals are made to licensed, trained, and qualified counselors to support the behavioral changes required to enhance recovery efforts.

(C) Twelve-Step or Other Mutual-Help Groups

The use of 12-step or other mutual-help groups should be encouraged. Sometimes these groups are unfamiliar with opioid addiction treatment. OTP/MAT/OBOT providers can establish their own 12-step or other mutual-help programs and should identify those groups that are accepting of maintenance pharmacotherapy.

(D) Counseling on HIV Infection and Other Conditions or Diseases of Public Health Importance

- (a)** Programs provide counseling on HIV infection and other prevalent infectious diseases, such as hepatitis, sexually transmitted infections, and TB. Counseling also includes infectious disease prevention for at-risk patients, and the need for patients to adhere to treatment and to communicate honestly with the provider when treatment has begun.
- (b)** Programs provide risk reduction education to patients.

(E) Medical Services

Providing basic primary care or integrated Psychiatric care onsite is highly recommended but not required. Programs make referrals for medical and/or psychiatric treatment when indicated. Staff involved in patient coordination should be appropriately trained and/or credentialed. Within OTP programs, though occasionally in OBOT/MAT programs where daily dosing is witnessed, medications that have their effectiveness enhanced by directly observed therapy (DOT)—such as TB medications and psychiatric medications—can be effectively dispensed with the daily opioid dose. Likewise, psychotropic medications, which are indicated but subject to abuse, may be given through DOT.

9. Drug Testing

- (1)** Programs use drug and alcohol screening and testing as aids in monitoring and evaluating a patient's progress in treatment.
- (2)** All treatment personnel in a medication-assisted treatment program understand the benefits and the limitations of toxicological testing procedures.
- (3)** Programs collect all urine or other toxicological specimens in a therapeutic context
- (4)** Clinicians should determine the drug-testing regime by analyzing community drug-use patterns and individual medical indications. Testing may include opiates, benzodiazepines, barbiturates, cocaine, marijuana, methadone (and its metabolites), amphetamines, and alcohol, but testing is not limited to these substances.
- (5)** Per OTP regulations it is strongly recommended that barbiturates and alcohol be included in drug screening and testing panels. Alcohol is the most widely used mood-altering substance in the United States, and barbiturates are often prescribed for detoxification and chronic seizure disorders. However Benzodiazepines appear to be more commonly prescribed in Vermont so clinical judgment should be exercised

- (6) Program staff addresses results of toxicology testing with patients promptly. Programs document in the patient record both the results of toxicology tests and followup therapeutic interventions.
- (7) After the patient's initial admission drug testing, clinicians determine the frequency of toxicological testing by evaluating the clinical appropriateness for each patient in relation to the patient's stage in treatment. For patients receiving services from multiple providers, attention to coordinating/sharing toxicology results is expected
- (8) Clinicians consider confirming the results of drug screening tests with additional testing. Treatment programs establish procedures for addressing potentially false positive and false negative urine or other toxicology test results following principles outlined in TIP 43, "Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs" (CSAT 2005, chapter 9)
- (9) Per federal regulations related to urine toxicology results, 42 CFR § 8.12(f) *Drug abuse testing services*. **OTPs** must provide adequate testing or analysis for drugs of abuse, including at least **eight random drug abuse tests per year**, per patient, in maintenance treatment, in accordance with generally accepted clinical practice. For patients in short-term detoxification treatment, the OTP shall perform at least one initial drug abuse test. For patients receiving long-term detoxification treatment, the program shall perform initial and monthly random tests on each patient.

10. Detoxification, Tapering, or Medically Supervised Withdrawal

As clinically appropriate, a physician may admit a patient to OTP/MAT/OBOT for "detoxification" treatment, hereinafter referred to as "medically supervised withdrawal." "Medically supervised withdrawal" refers to a gradual reduction, or tapering, of the medication dosage over time under the supervision of a physician, to achieve the elimination of tolerance and physical dependence to opioid medications.

A. Medically Supervised Withdrawal From Medication (Voluntary)

- (1) Medically supervised withdrawal is conducted
 - (a) As a voluntary and therapeutic process, agreed on by physician and patient or
 - b) In response to the request of the patient—against the advice of the physician, counselor, and other staff—that is, against medical advice (AMA).
- (2) The physician initiates voluntary supervised withdrawal from medication-assisted treatment in collaboration with and at the request of the rehabilitated patient. Voluntary supervised withdrawal is completely different and distinct from involuntary tapering or administrative withdrawal or other types of medically supervised withdrawal.
 - (a) In initiating medically supervised withdrawal, the physician reduces dosages of medication at a rate well tolerated by the patient and in accordance with sound clinical judgment.

- (b) For women of childbearing potential, the physician conducts an assessment for pregnancy and reviews the results of a pregnancy test before initiating medically supervised withdrawal (*See 2. I. (5) (d)—The physician should not initiate withdrawal before 14 weeks' or after 32 weeks' gestation, per OTP guidelines for methadone*).
- (c) The OTP/OBOT/MAT program resumes medication-assisted treatment if the patient experiences impending or actual relapse, as applicable and resource available.

(B) Support of Medically Supervised Withdrawal

The following program policies and procedures promote successful medically supervised withdrawal, whether conducted with or against medical advice:

- (a) Increased counseling is available prior to discharge
- (b) Participants are encouraged to attend a 12-step or other mutual-help program that is sensitive to the needs of patients receiving medication-assisted treatment.
- (c) Consideration/discussion of utilizing alternative pharmacology following medically supervised withdrawal to support continued recovery following cessation of present medications (eg. Nalrexone, vivitrol)

(C) Additional Considerations for Medically Supervised Withdrawal Against Medical Advice

- (a) The patient has the right to leave treatment when he or she chooses to do so. The program explains the risks of leaving treatment and offers information about or referral to alternative treatment options.
- (b) In the case of a patient who leaves an OTP program abruptly, the program may readmit the patient within 30 days without repeating the initial assessment procedure required by regulation 42 CFR § 8. MAT/OBOT providers utilize their discretion though consideration for pregnancy testing for women of child bearing age should be considered.
- (c) The program documents the issue that caused the patient to seek discharge and steps taken to avoid discharge.
- (d) If medically supervised withdrawal fails, the physician considers initiating maintenance treatment in conjunction with the patient and ancillary treatment providers
- (e) In the case of a pregnant patient, the program keeps the physician or agency following the patient for prenatal care informed, consistent with privacy standards of 42 CFR 2.

11. Administrative Withdrawal and Discharge

A major goal for programs is to retain patients for as long as they can benefit from treatment and express a desire to continue it. Because retaining the patient is not always possible, programs provide procedures for administrative withdrawal that employ the principles involved in medically supervised withdrawal from medication. Administrative withdrawal is usually involuntary. When a program makes the decision administratively to discharge a patient from pharmacotherapy, the program offers a humane schedule of medically supervised withdrawal, using sound clinical judgment. A suggested medically supervised withdrawal schedule for OTP administrative withdrawal is generally a minimum of 30 days, but the physician may adjust this timeframe depending on clinical factors. For OBOT/MAT providers, taper schedules ranging from 3-28 days are available while longer than 30 day tapers may also be individually tailored as needed based upon clinical presentation and monitoring of the patient.

(1) Administrative withdrawal may result from

- (a)** Nonpayment of fees. Remedies may include referral to a more affordable treatment program. As a last resort, programs provide a humane schedule of medically supervised withdrawal.
- (b)** Disruptive conduct or behavior. Such behaviors may have an adverse effect on the program, staff, or patient population of such gravity as to justify the involuntary medically supervised withdrawal and discharge of a patient, despite an extremely poor prognosis. Disruptive behaviors include violence, direct threat of violence, dealing drugs, repeated loitering, and flagrant noncompliance, resulting in an observable, negative impact on the program, staff, and other patients. Per OTP guidelines, patients who exhibit disruptive behaviors should receive a mental health evaluation and referral, as appropriate, prior to administrative withdrawal while MAT/OBOT providers should be clinically monitoring of potential mental health symptoms.
- (c)** Incarceration or other confinement.

(2) The OTP/MAT/OBOT provider takes into consideration all factors affecting the patient on a case-by-case basis, and documents procedures for any involuntary terminations of patients.

(3) Efforts made regarding referral or transfer of the patient to a suitable alternative treatment program should be documented, inclusive of psycho-social support referrals.

(4) The program makes specific efforts to ensure referrals are followed through to completion for the pregnant patient in the rare event the patient is administratively withdrawn and discharged. Provider(s) should carefully follow up with both patient's pregnancy and opioid dependency. It may be helpful for the program to establish prearranged agreements for treatment for this very purpose.

(5) OBOT/MAT providers determine during the process of on-going assessment that the patient is not appropriate for office based treatment and may be better served by other treatment modalities. Indicators of this may include: continued use of substances, confirmed medication diversion, and /or lack of response to the treatment plan.

P. Continuing Care

(1) An essential part of treatment is continuing care that includes discharge planning and relapse prevention.

(2) Continuing care also includes procedures that address patients' physical and mental health problems following medically supervised withdrawal.

(3) The treatment program/provider provides for continuing care following the last dose of medication, including making a referral for continuing outpatient care and planning for reentry to maintenance treatment if relapse occurs and resumption of care continues to be appropriate.

IV. Special Populations/Circumstances of Care

1. Additional Treatment Planning Considerations

(a) Management of Co-Occurring Disorders

When possible and appropriate, co-occurring disorders (poly-drug, medical and/or mental health) are concurrently managed onsite. Research demonstrates coexisting conditions, especially in patients from disenfranchised populations, are most effectively treated at a single site. However if the appropriate level of expertise is not available within the OTP/MAT/OBOT program, then appropriate patient referrals are made.

(B) Alcohol and Other Drug Abuse

(a) When clinically appropriate, programs manage concurrent abuse of other drugs within the context of the medication-assisted treatment, following principles described in TIP 43, "Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs" (CSAT 2005).

(b) Program staff members are knowledgeable about current effective strategies for treating alcohol, cocaine, and other drug abuse.

(c) Ongoing multidrug abuse is not necessarily a reason for discharge, patients engaging in such multidrug use receive careful evaluations to determine the most therapeutic course of treatment, in light of the fact that many patients (and communities) continue to benefit from medication-assisted treatment even when the patients are not fully abstinent from all drugs of abuse. The treatment decision for poly-drug-abusing patients should take into account the patient's condition and the treatment team's best clinical judgment. Treatment programs coordinate care with providers outside the OTP/OBOT/MAT program who prescribe medication with abuse potential.

(C) Care of Patients With Mental Health Needs

Treatment programs

- (a) Ensure that patients with mental health needs are identified through the assessment process and referred to appropriate treatment as needed
- (b) Ensure that patients are monitored during withdrawal and/or discharge for emergence of symptoms of mental illness.
- (c) Establish and use linkages with mental health providers in the community.
- (d) Establish a mechanism to evaluate mental health medication jointly with the mental health provider. If possible and if indicated, programs may even dispense such medications in conjunction with the daily dose of opioid medication.

(D) HIV Testing and Care of HIV-Positive Patients

- (a) Programs develop and implement a plan for educating patients about HIV/AIDS, testing procedures, confidentiality, reporting, followup care, counseling, safer sex, social responsibilities, universal precautions, and sharing of intravenous equipment.
- (b) Programs offer people living with HIV/AIDS options to promote maximum benefits of medication-assisted treatment during the course of HIV/AIDS treatment, including addressing medication side effects and toxicity, establishing linkages and referrals with HIV/AIDS treatment programs and social support services
- (c) The treatment program and the provider responsible for HIV/AIDS medication management work together to monitor and case manage medication adherence and adverse events.

(E) Treatment Considerations for Viral Hepatitis

- (a) Patients who test positive for viral hepatitis receive a referral for further evaluation and treatment, if necessary. Patients who test negative are immunized against hepatitis A and B, as appropriate, and against other viral hepatitis strains as those vaccines become available. For patients identified positive for HCV and who require antiviral therapies, coordination of care should occur. Counseling/training around blood-borne pathogens should be available to staff and patients

(F) Treatment Considerations for Smoking Cessation

Treatment programs address smoking and tobacco cessation with patients as an integral part of their treatment.

(G) Cultural Competency

- (a) Programs develop and implement written nondiscrimination policies to ensure equal access to treatment for all persons in need, regardless of race, ethnicity, gender, disability, age (with specific reference to policies for minors), or sexual orientation. Programs are sensitive to the culture and values of patients in treatment.

(H) Criminal Justice Issues

- (a) Programs develop procedures to coordinate with agents of the criminal justice system on behalf of patients.

(I) General Principles Regarding Care of Women in Treatment

- (a) The policies and procedures of each treatment program reflect the specific needs of female patients.
- (b) All staff members receive training in the specific characteristics and needs of women participating in their particular treatment program, assuring sensitivity to trauma and/or violence related issues and OTP/MAT/OBOT programs either have internally or through referral the ability to coordinate gender specific psycho-social supports

(J) Family Needs

- (a) Treatment programs provide opportunities for involvement of family and significant others in therapy, as appropriate
- (b) Treatment programs offer onsite education and training for all male and female parenting patients, or have the ability to refer patients to appropriate parenting skills services and /or childcare services.
- (c) Program services include reproductive health education for all patients and appropriate referrals, as needed, for contraceptive services.
- (d) Children of patients in medication-assisted treatment may have special mental health and cognitive needs, especially if there has been physical or sexual abuse or neglect. Treatment programs offer referrals to appropriate resources and/or parenting support groups (CSAT 2005).

(K) Alternative Therapies

Programs support patient choice in seeking alternative therapies while providing appropriate guidance in the process. Programs may provide culturally appropriate or popular and nonharmful alternative therapies as indicated (e.g., providing a space for sweat lodge ceremonies in a rural clinic serving Native Americans, or offering acupuncture).

(L) Treatment of Other Diseases and Conditions of Public Health Interest

- (a) Programs should treat patients diagnosed with disorders that require reporting to public health departments or refer those patients for further evaluation and treatment elsewhere. Examples of these types of diseases include TB and STDs. Programs should ensure that each patient has access to low-cost or free immunizations recommended by the CDC.

- (b) Staff members should become knowledgeable about existing and emerging diseases of a public health interest and educate patients about these conditions. Treatment programs are continually prepared to review and modify clinical approaches—and to address related mental health issues for patients and staff—as the public health environment changes.
- (c) Programs exchange information appropriately with the providers and health departments caring for the patients with reportable diseases or conditions, taking into account informed

2. Pain Management for Opiate replacement patients

(A) Methadone

1. Management of chronic pain in the methadone-maintained patient includes consultation with a specialist in pain medicine when possible and appropriate.
2. Management of acute pain in the methadone-maintained patient entails
 - a. Continuation of the regularly scheduled methadone dose
 - b. Additionally prescribing adequate doses of appropriate medications, narcotics as needed to address pain symptoms

(B) Pain Management in Buprenorphine Patients

- (a) Due to the high affinity of Buprenorphine to the receptor sites, achieving pain relief in Buprenorphine maintained patients presents complications. Therefore, due to the potential options, depending upon patient dose and situation, a copy of pain management guidelines is attached to this document. For additional support, please contact the Vermont Department of Health, Division of Alcohol and Substance Abuse services for referral information and support

Note: The suboxone and subutex formulations of Buprenorphine are not Medicaid approved analgesics, rather they are only approved for the treatment of opioid dependence.

(b) Other Principles of Pain Management

- (i). OTP/OBOT/MAT treatment programs make careful diagnostic distinctions between the physical dependence associated with chronic administration of opioids for relief of pain and the disease of opioid addiction.

- (ii) Generally, patients are not admitted to medication-assisted treatment to receive opioids only for pain, but there are exceptions to this principle especially if no pain treatment settings are available in the community. In MAT/OBOT programs, patients with only pain issues should not be treated in the context of addiction.

(iii) Patients with both chronic pain disorder and addiction should receive treatment from pain and addiction medicine specialists employing a multidisciplinary-team approach or from a provider with expertise in both areas of practice

(iv) OTP patients who are diagnosed with physical dependence and a pain disorder are not prohibited from receiving medication-assisted treatment for either maintenance or medically supervised withdrawal in an OTP setting. Similarly, addiction patients in medication-assisted treatment may receive both medication-assisted treatment and adequate doses of opioid analgesics for pain; the regulations and treatment guidelines permit administering both when medically necessary.

(3) Pregnant and Postpartum Patients

NOTE: As of this writing, both methadone and buprenorphine are Pregnancy Category C drugs, which call for a careful risk/benefit analysis, but for which there is no known harm to the human fetus when medication is taken as directed and relapse is avoided.

(A) OTP providers will ensure:

- (a)** The treatment program gives priority to pregnant women who seek treatment and documents on an intake log or in other accessible program records the reasons for denying admission to any pregnant applicant. If treatment is denied, notification to the Vermont Dept. of Health, Office of Alcohol and Drug Abuse programs is expected within 48 hours.
- (b)** The treatment program ensures that every pregnant patient has the opportunity for prenatal care, provided onsite or by referral to appropriate health care providers, with appropriate releases signed by the patient for shared information.
- (c)** If appropriate prenatal care is not available onsite or by referral, or if the pregnant patient cannot afford care or refuses prenatal care services, the treatment program, at a minimum, offers her basic prenatal instruction on maternal, physical, and dietary care as part of the counseling services and documents the provision of these services in the clinical record.
- (d)** If a pregnant patient refuses direct prenatal services or appropriate referral for such care, the treating physician in the treatment program may use informed consent procedures to have the patient formally acknowledge, in writing, that the program offered these services but the patient refused them.
- (e)** For pregnant women in methadone treatment, the program
 - (a)** Maintains patients who become pregnant during treatment on the pre-pregnancy dosage, if effective, and applies the same dosing principles as used with any other non-pregnant patient.
 - (b)** Ensures that the initial methadone dose for a newly admitted pregnant patient and the subsequent induction and maintenance dosing strategy reflect the same effective dosing protocols used for all other patients.

- (c) Monitors the methadone dose carefully, especially during the third trimester when pregnancy-induced changes in the rate at which methadone is metabolized or eliminated from the system may necessitate either an increased or a split dose.
- (d) In general, detoxification during pregnancy is not recommended or considered the best practice. If a pregnant patient elects to withdraw from methadone and stays in the program, a physician experienced in addiction medicine supervises the withdrawal process with regular fetal assessments, as appropriate, for gestational age, as part of the withdrawal process. The physician should not initiate withdrawal before 14 weeks' or after 32 weeks' gestation.
- (f) The program supports the decision to breast-feed during methadone treatment, unless medically contraindicated, for example, by the presence of HIV or HTLV I or II infection in the mother. The treatment program should document appropriate counseling and informed decision making between provider and patient to ensure that issues mentioned in the latest patient information sheets and product inserts for methadone are covered and understood.
- (g) The treatment program establishes and implements policies and procedures, including informed consent, to ensure appropriate followup and primary care for the new mother and well-baby care for the infant. Informed consent refers to the patient's agreement to receive treatment as well as agreement to release information to and obtain information from pertinent health care providers.
- (h) If a pregnant patient is discharged, the program should identify the physician to whom the person served is being discharged. The program staff records the name, address, and telephone number of the physician who will be caring for the patient after discharge.

(B) For OBOT/MAT Providers with Buprenorphine:

- (1) Should questions arise regarding the treatment of pregnant women with Buprenorphine, please contact the Vermont Department of Health, Office of Alcohol and Drug Abuse Programs at (802)651-1550 who can assist providers with resources and support.
- (a) A risk/benefit discussion providing informed consent to each patient is expected upon confirmation of pregnancy. For existing patients on OBOT/MAT, transition the patient to Subutex if, after offering informed consent related to pregnancy, the patient desires to continue on MAT/OBOT. Otherwise a referral for Methadone should be made. It is HIGHLY recommended that opiate dependent women be referred to high risk obstetrics providers given the heightened risk of pregnancy and obstetrical complications. Additionally, OBOT and MAT providers should coordinate this care with adherence to pre-natal care being a strong factor in the consideration of continued office based care.

C. Concurrent Pregnancy and HIV Infection

- (a) Pregnant women in OTP/MAT/OBOT treatment with concurrent HIV infection are subject to the same policies and procedures established for all HIV-infected patients in treatment and receive the same services.
- (b) Treatment programs offer pregnant patients with HIV diagnoses the same treatment opportunities and services, directly or by referral, as HIV-diagnosed patients who are not pregnant.
- (c) Treatment programs ensure that all pregnant patients with concurrent HIV infection are (1) informed that HIV medication treatment is currently recommended to reduce perinatal transmission and (2) provided with appropriate referrals and case management for this treatment.

(9) Care of Adolescents in Treatment

- (a) For OTP consideration, "A person under 18 is required to have had two documented attempts at short-term medically supervised withdrawal (detoxification) or drug free treatment to be eligible for maintenance treatment. The program physician shall document in the patient's record that the patient continues to be or is again physiologically dependent on narcotic drugs. No person under 18 years of age, except an "emancipated minor", may be admitted to a maintenance treatment program unless a parent, legal guardian, or responsible adult completes and signs consent form, Form FDA 2635 "Consent to Methadone Treatment."
- (b) Programs tailor assessments to the developmental stage of the patient
- (c) Programs develop and implement policies to ensure that adolescents are not harassed or exploited by older patients or staff.
- (d) Buprenorphine within the office based setting may be prescribed to individuals age 16 and older based upon the clinical judgment of the physician. It is **strongly** suggested that if buprenorphine maintenance is being considered (rather than medically supervised withdrawal) that physicians consult with an addiction specialist.

V. Participation in Opioid (pharmacological) Therapy Research Activities

(a) Patients have the right to give informed consent prior to being involved in research projects, and the right to retain a copy of the informed consent form.

(b) Patients have the right to full disclosure of information about treatment and medication, including accommodation for those who do not speak English, or who are otherwise unable to read an informed consent form.

(c) Programs are encouraged to participate in research activities as long as they do not compromise the integrity of the treatment process.

(d) Research conducted in the treatment program does not compromise the integrity of the treatment process.

(e) The director of the treatment program has the authority to consider participation in proposed research or study that is based on sound scientific principles.

(f) All research involving human subjects is conducted in accordance with accepted Federal human subject protection standards.

(g) Treatment and other services are not jeopardized for any patient who refuses to participate in research activities.

Appendices 1: Guidelines for Dosing

II. Induction

Induction onto buprenorphine is considered to be an ambulatory procedure not requiring an inpatient admission unless there are medical complications or other extenuating circumstances. The induction steps listed below are guidelines intended to ensure close monitoring during the initial phases of treatment. Dosing guidelines based on reported drug use can be helpful in targeting eventual final buprenorphine doses. (See *Guide for Dose Targets*, end of this section.)

General Guidelines for patients physically dependent on opioids:

1. Begin induction early in the week.
2. Plan on 3-5 days for stable dosing.
3. Patient's last reported use should have been at least 6 hours prior to induction.
4. MAKE SURE THE PATIENT IS NOT ON METHADONE as buprenorphine may cause an acute withdrawal syndrome; if patient is on methadone, see below protocol for long acting opiates.
5. Day 1: Give the patient a prescription for #2 2mg Suboxone tablets.
6. Patient takes the prescription to the pharmacy and returns to the office with the medication.
7. Patient takes the tablet and lets it dissolve under the tongue for 5 minutes with no talking, drinking, or swallowing.
8. Target buprenorphine dose range should be 12mg to 16mg per day, with a recommended maximum of 16mg daily.
9. If more than 8mg are needed, gradually increase the dose in 2mg increments over the next several days.
10. The patient's condition before dosing time is one of the best ways to assess adequacy of the dose. (Refer to *Appendix E, Clinical Opiate Withdrawal Scale (COWS)*, for assessing withdrawal symptoms before the first dose is given and throughout the Induction period.

Guidelines for patients **NOT** physically dependent on opioids (e.g., coming out of incarceration or otherwise high risk for relapse):

First dose: 2mg sublingual buprenorphine.
Monitor for 2+ hours and consider 2mg incremental dosage increases over the next several days.

Specific recommendations for patients dependent on **SHORT ACTING** opioids:

1. Instruct patient to abstain from any opioid use for a minimum of 6-12 hours so they are in mild withdrawal at time of first buprenorphine dose. *Note:* If patient is not in withdrawal, have them wait and reassess their use or abstinence over past 12-24 hours or return another day.
2. Week 1, Day 1: First dose: 2mg sublingual Suboxone (combination therapy) with direct observation after 5 minutes that the medication is dissolved.
3. Monitor in office for up to 2 hours to insure no vomiting and tolerance of the dose.
4. Send patient home with the additional 2 mg dose and redose in 2-4 hours if withdrawal subsides, then reappears. Maximum dose for first day: 4 mg.
5. Day 2: Patient returns to office. If looks well, renew same dose of 4 mg for the next 2 days. If shows signs of withdrawal based on CINA Scale and/or Clinical Opiate Withdrawal Scale, prescribe #4 2 mg tabs, have patient go to pharmacy, return to office with medication and take 3 pills in front of nurse; wait 5 minutes and then send home and redose later in the day if needed. Maximum dose for second day: 8 mg.
6. Day 3: If patient needed the dose adjustment on Day 2, have them return for direct observation pre-dose and if looks well, give prescription for 8 mg tabs for 3 days and send them home. Have patient return for follow-up in 2 days. If showing signs of withdrawal on CINA score, give a prescription for 10 mg to take for the next 3 days.
7. Day 4: If patient stable on 4 mg on Day 2, make sure they are well and give one week's supply to take at home. If dose needs adjustment, increase to 6 mg and give one week's supply to take at home.
8. Day 5: If patient from Day 3 shows any signs of withdrawal, give an additional 2 mg dose per day and give a week's supply. Maximum dose: 12 mg.
9. Week 2: Before renewing the week's supply, have patient come in pre-dose to assess whether any adjustment in dose is needed; if needed, adjust by 2-4 mg. Maximum dose: 16 mg.

NOTE: If a patient has insurance co-pay, consider writing prescription for #16 pills of 2 mg for a minimum of 4 days of induction. The patient can bring the pills in each day for directly observed dosing to make sure they are taking them. THE MOST CRITICAL THING IS MAKING SURE THE PATIENT IS TAKING THE CORRECT DOSE. DOING THIS EARLY WILL REDUCE DIVERSION LATER ON.

Specific recommendations for patients dependent on **LONG ACTING** opioids:

1. Doses of methadone should be decreased to a stable state of 30mg of methadone or equivalent.
2. The following dose equivalents are target doses, not starting doses:

Methadone 40 mg = Buprenorphine 8 mg
Methadone 60 mg = Buprenorphine 12 mg
Methadone 80 mg = Buprenorphine 16 mg
3. Begin Induction 24 hours after last methadone. No additional methadone given after Induction begins.
4. Follow same protocol for short acting opioids, but faster dose adjustments may be needed daily for the first week.

III. Stabilization

Patient should receive daily dose until stabilized.

An option is to shift to alternate day dosing, by increasing the amount on the dosing day by the amount not received on the intervening days (see #5 below).

1. Urine screens should be done once a week.
2. Non-attendance for counseling for more than two consecutive sessions should trigger an automatic call from the counselor. The physician should schedule an office visit with the patient to make sure the patient understands that failure to follow through with counseling jeopardizes treatment and puts them outside of "good standing."
3. Write 7 days' worth of medication at a time for 2 months.

IV. Maintenance and Follow Up

4. Once patient has remained compliant with counseling and physician visits, has not had any mishaps with the Suboxone, and feels ready to do so, extend the prescriptions to 14 days for the next 2 months.
5. A patient may choose to take Suboxone every 2 or 3 days. The dose is doubled or tripled, depending on the time frame, and taken all at once. This is very effective in controlled settings, such as dispensing by a family member or clinic, but may be done for patient preference only.
6. After a period of time that varies with each patient but should reflect compliance with treatment, a prescription for 30 days may be written. Pill counts may be a useful monitoring tool at this point.
7. Urine drug testing is now available for determining the presence of the buprenorphine metabolite and this may be used as a clinical tool to encourage success in treatment, as well as a precautionary measure for avoiding diversion.

V. Tapering Patients off a Stable Buprenorphine Dose

There may be well-stabilized patients who desire to be withdrawn from buprenorphine medication. There is evidence a relatively quick taper from buprenorphine may be advantageous and will not result in relapse at greater rates than for patients weaned more slowly. Research comparing relatively shorter taper periods (7-days) with relatively longer ones (28-days) found a higher percentage of patients in the 7-day taper group were opioid free at the end of the taper, and both self-reports and physician observation of withdrawal symptoms and craving were no different between the two groups. In addition, no differences between the two groups were found in the rate of relapse to illicit opioid use three months after the taper period ended. The following table provides taper schedules for both taper periods.

SUBOXONE TAPER REGIMEN FOR TWO STUDY TAPER GROUPS

(*dose noted is the dose of buprenorphine)

		7-Day Taper Period				28-Day Taper Period	
*Stabilization Dose:	8 mg	16 mg	24 mg		8 mg	16 mg	24 mg
<u>Study Day</u>							
1	8	16	24		8	16	24
2	6	12	20		8	16	24
3	6	10	17		6	12	20
4	4	8	12		6	12	20
5	4	4	8		6	12	20
6	2	2	4		6	10	16
7	2	2	2		6	10	16
8					6	10	16
9-11					6	8	12
12-14					4	8	10
15-16					4	6	8
17-19					4	4	6
20-22					2	4	4
23-25					2	2	2
26-28					2	2	2

Ling, W., et al., Buprenorphine Tapering Schedule and Illicit Opioid Use, *Addiction*, **104**, 2009.

VI. Detoxification

Rapid detox: Three days or less

- Low doses of buprenorphine given 2-3 times daily
- More effective in suppressing withdrawal than clonidine
- Long term efficacy not well documented
- Not recommended due to poor outcomes and should only be done when there is a compelling reason for patient to be detoxed quickly (e.g., out of country travel, imminent incarceration)

Moderate detox: 30 days or less

- Raise dose daily over 4 days to equal opiates taken, then decrease by 2 mg every 1-2 days until weaned
- Better tolerated than clonidine
- Few studies of buprenorphine for this time period

Long detox: more than 30 days

- Raise dose daily over 4 days to equal opiates taken, then reduce by 2 mg weekly until weaned
- Not well studied but some evidence suggests this approach is more efficacious than briefer ones, especially if naltrexone is started after an appropriate wash out period

GUIDE FOR DOSE TARGETS

<u>Buprenorphine Doses</u>	<u>Oxycodone</u>	<u>Morphine</u>	<u>Heroin</u>	<u>Methadone</u>
2 mg	30 mg	60 mg	<u>1-2 bags</u>	10 mg
4 mg	60 mg	120 mg	<u>3 bags</u>	20 mg
6 mg	90 mg	180 mg	<u>4 bags</u>	30 mg
8 mg	120 mg	240 mg	<u>6 bags</u>	40 mg
12 mg	180 mg	360 mg	<u>8 bags</u>	60 mg
16 mg	240 mg	480 mg	<u>10 bags</u>	80 mg

Appendices 2: Buprenorphine and Pain Management

VII. Management of Acute Pain in Patients Receiving Buprenorphine

Management of acute pain in patients receiving buprenorphine products (either mono therapy or combination buprenorphine/naloxone) is a common scenario. Although there are some published articles, no approach has been rigorously tested. However, commonly accepted principles to follow have developed over the years. The following article also may be of interest. Note: As with all patients with pain, non-pharmacologic therapies and non-opioid analgesics should be used when safe and likely to work

Buprenorphine blocks opiate receptors, making them unavailable for further opiate analgesic effects. The dose of buprenorphine predicts how many of the receptors are blocked; generally, any buprenorphine dose above 10 mg will block opiate analgesics for pain (per Vermont Buprenorphine Guidelines 2010).

One potential option may be: a patient who will experience acute pain from surgery or a recent injury should have the dose of buprenorphine reduced to 8 mg; to make up the opiate debt, the remaining amount of buprenorphine is converted to short acting opiates. (Vermont Buprenorphine Guidelines 2010)

For example, carpal tunnel release surgery is planned for a patient taking 16 mg of buprenorphine. The typical post operative treatment for this surgery is 10 mg of oxycodone every 4 hours for 3 days. Therefore, the patient would stop taking one of the 8 mg buprenorphine tablets the day of surgery. A prescription for 30 mg of oxycodone to be taken 4 times a day for 3 days would be provided to MAKE UP THE OPIATE DEBT FROM THE 8 MG OF BUPRENORPHINE that has been stopped. In addition, post operatively the patient would take 10 mg of oxycodone every 4 hours for the 3 post operative days.

After the end of the 3 day post operative period, the patient resumes taking the 8 mg of buprenorphine that had been stopped, discontinues the replacement oxycodone, and begins using non-opiate analgesics. Of course, in cases with persistent pain the above regimen could be continued for a longer period of time, and for some procedures several weeks might be needed. Seeing the patient every 3-5 days to manage their pain is most effective as it provides the patient with stability and prevents relapse and misuse of opiates.

Another potential option may be: For patients with moderate to severe pain who are expected to require opioid analgesic therapy for the short term, federal guidelines recommend holding the buprenorphine and starting short acting opioid agonists. While the buprenorphine's effects diminish (20-60 hours), the patient may require higher opioid doses to compete with the presence of buprenorphine on mu-opioid receptors. The patient should be monitored carefully in the initial period to titrate the opioid agonist dose downward as its effect becomes greater. Before restarting buprenorphine, the patient should be opioid-free for 12-24 hours to avoid precipitating withdrawal. This process should be overseen by an approved buprenorphine provider. (Medical College of Wisconsin)

Another option is to continue buprenorphine and use short-acting opioid agonists at high enough doses to overcome buprenorphine's partial agonism. Opioids that have a higher intrinsic activity at the mu-opioid receptor, including morphine, fentanyl, or hydromorphone, are all options, while opioids with less efficacy such as hydrocodone or codeine should be avoided. (Medical College of Wisconsin)

In a patient who is expected to have an ongoing need for pain management, consider replacing buprenorphine with methadone therapy for opioid addiction. For analgesia, additional methadone or other 'full' mu-opioid receptor agonists can then be added without problems related to use of a partial opioid agonist. (Medical College of Wisconsin)

